

KRISHGEN PUDGALA

PARTNER FOR PRECISION DIAGNOSTICS

ACCURATE AND RELIABLE IVD KITS THAT GUARANTEE LONGEVITY, SPECIFICITY, SENSITIVITY AND ACCURACY.

ABOUT US

Krishgen Pudgala is a leading biotech manufacturer and distributor established since 2003. We are the leading Indian manufacturer of ELISA kits for life sciences with 3000+ product citations.

Our products are manufactured in our state of the art IVD facility set up over 10,000 square feet in Navi Mumbai, Maharashtra, India. The facilities are fully certified and ready equipped as per Maharashtra FDA, CDSCO (Delhi) and is certified ISO 13485. We follow ISO 9001:2016 standards for all documentation.



Visit Our website

MANUFACTURING AND QUALITY ASSURANCE

Our products are manufactured in our state of the art IVD facility set up over 10,000 square feet in Navi Mumbai, Maharashtra, India. Equipped with clean rooms and separate air handling units (AHUs) for different products (ELISA kits), we ensure there is no cross over contamination. The clean room floors are epoxy coated, use HEPA filters and positive monitored air-pressure to reduce bio-burden in the production areas.

With our expertise in developing some of the most unique assays worldwide, our IVD ELISA kits have the biggest advantage of being fully validated. Our products comply with quality certifications including ISO0011, ISO13485, CDSCO, and CE.



Perfect Solutions To Your Diagnostic Demands!

022 - 49198781 | sales@krishgenpudgala.com

www.krishgenpudgala.com

Unit No #318/319, Shah and Nahar. Off Dr. E Moses Road, Worli, Mumbai 400018

ABOUT KRISHGEN

Krishgen Pudgala LLP is an in-vitro diagnostic device manufacturer that is part of the Krishgen Group. Our expertise in developing assays stems from our parent company, Krishgen Biosystems, that has developed and manufactured these assays for research purpose.

Having worked with antibodies, proteins, DNAs and RNAs since 2003, our years of experience has helped us offer the best solutions for diagnostics. Our research encompasses many technologies including protein expression, peptide designing, antibodies generation, immunoassays, immunochromatography and molecular biology with PCR, RT-PCR, SSP and NGS.

We work with leading diagnostics labs and hospitals across the country in both the government and private sectors. Our customers include:



MANUFACTURING AND QUALITY ASSURANCE

Our products are manufactured in our state of the art IVD facility set up over 10,000 square feet in Navi Mumbai, Maharashtra, India. Equipped with clean rooms and separate air handling units (AHUs) for different products (rapid kits, ELISA kits and PCR kits), we ensure there is no cross over contamination. The clean room floors are epoxy coated, use HEPA filters and monitored positive air-pressure to reduce bio-burden in the production areas.

With our expertise in developing some of the most unique assays worldwide, our IVD ELISA kits have the biggest advantage of being fully validated.

Pudgala kits are validated for a high degree of sensitivity, specificity, accuracy and precision. We ensure that our kits not only operate during the shelf life but also ensure that stress tests are conducted on each individual components to ensure our kits offer ease-of-use and reproducibility.

QUALITY is a way of life for the Krishgen Pudgala team.

We are as good as our components. THE HEART of each ELISA is the antibodies and antigens. We partner with leading US and European manufacturers to ensure that we get the best reagents. A majority of our ELISA are sandwich formats using double antibodies to offer a high degree of accuracy and use monoclonal antibodies for higher specificity and reproducibility.

TECHNICAL SUPPORT

Not used to running ELISA or require product/technical support? No problem! With the plethora of technologies available, we can offer you online support in any part of the world. ELISA is a way of life for us. We can read your raw data and understand what is required to offer you support.

We use the best of the softwares and instruments to support you.

Our laboratory facilities include TECAN Safire2 multimode reader, Automated DS2 Dynex processors, Luminex Magpix Reader, plate readers, automated coating lines from Berthold Technologies, Germany and Moduline Systems, USA.

We use Magellan software and GraphPadPrism for our data reduction.

WHEN YOU BUY KRISHGEN PRODUCTS, YOU ARE IN SAFE HANDS.

**QUALITY
YOU CAN
TRUST**

ELISA KITS

Infectious Diseases

Adenovirus Antibody IgM
Adenovirus Antibody IgG
Epstein Barr virus Antibody IgG
Epstein Barr virus Antibody IgM
Brucella Antibody IgG
Brucella Antibody IgM
Chlamydia Pneumoniae Antibody IgA
Chlamydia Pneumoniae Antibody IgG
Chlamydia Pneumoniae Antibody IgM
Chlamydia Trachomatis Antibody IgA
Chlamydia Trachomatis Antibody IgG
Chlamydia Trachomatis Antibody IgM
Chikungunya Antibody IgG
Chikungunya Antibody IgM
Coxsackievirus Antibody IgG
Coxsackievirus Antibody IgM
Dengue Antibody IgG
Dengue Antibody IgM
Dengue Antigen NS1
Entamoeba Hystolytica Antibody IgG
HAV Antibody IgM
Helicobacter Pylori Antibody IgA
Helicobacter Pylori Antibody IgG
Helicobacter Pylori Antibody IgM
Helicobacter Pylori Stool Antigen
HEV Antibody IgM
Leptospira Antibody IgG
Leptospira Antibody IgM
Measles Virus Antibody IgG
Measles Virus Antibody IgM

Mumps Antibody IgG
Mumps Antibody IgM
Mycoplasma Pneumoniae Antibody IgG
Mycoplasma Pneumoniae Antibody IgM
Parvovirus B19 Antibody IgG/IgM
Parvovirus Antibody IgG
Respiratory Syncytial Virus Antibody IgM
Varicella Zoster Virus (VZV) Antibody IgG
Varicella Zoster Virus (VZV) Antibody IgM

TORCH

CMV IgG
CMV IgM
HSV 1 IgG
HSV 1 IgM
HSV 1/2 IgG
HSV 1/2 IgM
HSV 2 IgG
HSV 2 IgM
Rubella IgG
Rubella IgM
Toxo IgG
Toxo IgM

ELISA KITS

Auto-Immunity

ANA
Anti-Cardiolipin IgA
Anti-Cardiolipin IgG/IgM
Beta 2 Glycoprotein IgG/IgM
dsDNA
Anti-Phospholipid IgG/IgM
Gliadin Antibody IgA
Gliadin Antibody IgG
Anti-LKM

MPO (P-ANCA) Antibody IgG
PR3 (C-ANCA) Antibody IgG
Rheumatoid Factor IgM
Rheumatoid Factor IgG
Rheumatoid Factor IgA
Tissue Transglutaminase (tTg) IgA
Tissue Transglutaminase (tTg) IgG
ASCA IgG
ASCA IgA

Metanephrine

Metanephrine Urine
Nor-metanephrine Urine
Metanephrine Plasma
Nor-Metanephrine Plasma

Catecholamines

Adrenaline
Nor-adrenaline
Dopamine

Reproduction

17-OH-Proosterone
Anti Mullerian Hormone (AMH)
FSH
LH (Luteinizing Hormone)
Free Testosterone

Oncology

Chromogranin A

ELISA KITS

Sundries

Ferritin
IgE
Cotinine
Anti-Diuretic Hormone
Serotonin
25OH Vitamin D
Anti CCP

Interleukins

TNF-alpha (Tumor Necrosis Factor Alpha)
IFN-gamma (Interferon Gamma)
MCP-1 (Monocyte Chemotactic Protein 1)
IL-1 beta
IL-2
IL-4
IL-6
IL-8
IL-10
IL-12

Diabetes

Anti-GAD65 IgG
Anti-IA2
Human Insulin

ELISA Instruments

ELISA Reader - Multimode
Automated ELISA Washer

OUR CERTIFICATIONS

Our dedication to quality and reliability is reflected in the manufacturing licenses, quality documents, and company registration certificates that we have acquired. These certifications serve as a testament to our adherence to stringent regulatory requirements and our continuous efforts to deliver products of the highest standards.

By collaborating with us, you can trust that you are partnering with a company that places a strong emphasis on quality control, product integrity, and exceptional customer service.

[illegible][illegible]

FORM M-DS	
[See sub-article (4) of rule 20 and sub-rule (3) of rule 20]	
Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device	
Licence Number: N.2 1. MANUFACTURER'S ADDRESS: 18/015 SHIVAJI AND NAVABAI OFFICE FOR A MOSSES ROAD WORLI, MUMBAI, Mumbai City, Maharashtra (India). Tel: 02249187020 FAX: 02249187019 has been licensed to manufacture for sale or for distribution the medical devices detailed in the premises situated at: KSK Kollegal, Pappala L.P.P. U.S. 1, On: Sankariy Commenity Center, Village Dugudi, Pimpri-Chinchwad, Thane, Maharashtra (India) - 410502 Telephone No. 02249187017 FAX: 02249187019 2. Date of initial approval (Month/Year):	
3. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.	
ANNEXURE-1	
S.No.	Details of Device
1	Generic Name: HEPR (IGM ELISA) Model No.: HEPR Intended Use: The HEPR (IGM ELISA) is intended for the qualitative determination of HEPR in human serum and plasma. Class of medical device: Class B Material of construction: 1. Molecular Cloning Device (PCR) kit wells, 1 set, 2. Positive Control, 1 set 3. Negative Control, 1 set 4. Enzyme Conjugate, 0.5 ml, 5. 20x Wash Buffer, 20 ml and 100x Substrate, 12 ml 6.7. Stop Solution - 12 ml 8. Instruction Manual Dimensions (mm): Depth: 120 mm Height: 120 mm Weight: 400 gm Brand: Unregistered (registered under the Trade Marks Act, 1999) HEPR (IGM ELISA)

[illegible]

BSCIC
Bharat Standards Certification Institute

Certificate

RECEIVED DEVICE-
QUALITY MANAGEMENT SYSTEM

This is to certify:

KIRISHGEN PUDGALA LLP
REGD. OFFICE: PLOT NO.108/109, SHEELA NAGAR OFF. DR. AMBEDKAR
ROAD, WADI, MYSURU DISTRICT, KARNATAKA
UNIT NO.108/2, OM KANTA CHITRAPEY, OFF. MANOJ KANTA NIA,
VILLAGE BAPTOPE, BHEV-219 - 627 302, MAHARASHTRA, INDIA

hereby granting the Certificate Number: **01/07/2018 / 31/07/2020**

Intending to the Assessment of the organization, I have been found to be operating a Medical Device
Quality Management System which complies with the requirements of:

ISO 13485:2016

Design and Development, Manufacturing and Supply, Set-up and Support of In-Vitro
Diagnostic Reagents/Kits including Immunoassays, Antibodies and Molecular
Biology Based Kits, Instruments and Software for In-Vitro Diagnostic.
Excluded are: Instrument and Reagent Production and related Instrument, Software
In-Vitro Diagnostic Instruments and Software

For
BSCIC CERTIFICATIONS PVT.LTD.
Managing Director
Kirishgen Pudgala

Dr. S. S. Srinivas
BSCIC Representative

In case of Examination Failure and allowed to be re-examined, this Certificate shall be
Suspended/Withdrawn.

Signature of Managing Director: _____
Signature of BSCIC Representative: _____
Date: _____

Registrar of Companies
Mysuru

ISS-ISO
C

Version No. 1

Registered







KRISHGEN PUDGALA

PARTNER FOR PRECISION DIAGNOSTICS

Manufacturing Lab:

Unit No#1/2, Om Sainath Complex,
Off Mankoli Naka, Dopode Village, Bhiwandi.
Dist Thane



Focused on
Validation and Quality

300+ Products
across categories

50+ Channel
Partners pan-India

Custom ELISA
Calculator software for
Results Interpretation

Take a Virtual Tour of
our Manufacturing Lab.



Note: specific products are registered under different regulatory status. Contact us to know specific status of individual products.

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